

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC LANDAVAX SC

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<i>Pasteurella multocida</i> , A1 inactivated, strain X73	≥80 % clinically protected chicken*
<i>Pasteurella multocida</i> , A3 inactivated, strain P-1059	≥65 % clinically protected turkey*
Oil adjuvant	0.3 ml
Thiomersal	0.035 mg
Excipient QSP 1 dose of 0.5 ml	

(*) In the vaccinated birds (chicken and turkey and for the release control test) after challenge.

For a full list of excipients, see section "List of excipients".

3. PHARMACEUTICAL FORM

Emulsion for injection

4. CLINICAL PARTICULARS

4.1 Target species

Ducks (mulard ducks).

4.2 Indications for use, specifying the target species

In mulard ducks:

-Active immunization in order to reduce mortality, morbidity and clinical signs associated with infection caused by *Pasteurella multocida* capsule type A, serovars 1 and 3.

Onset of clinical protection: 3 weeks following the administration of second injection.

Duration of immunity: 10 weeks after the second injection.

4.3 Contraindications

Do not vaccinate sick birds.

4.4 Special warnings for each target species

No information is available on the possible interferences from the presence of maternal antibodies on the response to vaccination.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

To the user:

This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

iii) Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

Local reactions in the form of palpable swellings were observed at the injection site in 31% of the birds following the full vaccination program. These swellings can reach a maximum size of 10 cm² but tend to disappear progressively. Such swelling persists at least 5 weeks in 17% of the birds. These reactions do not require any particular treatment.

In the field a transient post-vaccination apathy may occur.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay and/or within 4 weeks before the onset of the laying period.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this product before or after another veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

Administer 1 dose of 0.5 ml by subcutaneous route through ply of the skin into the lower back part of the neck. Before administration, allow the vaccine to warm up to room temperature and shake it well. Administer under aseptic conditions!

Vaccination schedule:

First injection at 3 weeks of age.

Second injection: 3 weeks later.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

After administration of a double dose the swelling observed can reach 16cm² and affect up to 45% of the birds.

This reaction does not require any particular treatment.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATC vet code: QI01BB

Pharmacotherapeutic group: inactivated bacterial vaccines for duck

The vaccine stimulates active immunity against *Pasteurella multocida*, type A, serovars 1 and 3.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin light liquid

Sorbitan oleate

Polysorbate 80

Thiomersal

Sodium chloride

Potassium chloride

Disodium phosphate dihydrate

Potassium phosphate

Water for injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 month.

Shelf life after first opening the immediate packaging: 10 hours.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C -8 °C).

Do not freeze.

Store in a dry place protected from light.

6.5 Nature and composition of immediate packaging

Low density polyethylene vials
Nitrile rubber stopper
Aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

CEVA SANTÉ ANIMALE
10 AVENUE DE LA BALLASTIERE
33500 LIBOURNE
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

FR/V/3549036 6/2010

Vial of 50 ml containing 100 doses
Box of 1 vial of 50 ml containing 100 doses
Box of 5 vial of 50 ml containing 100 doses
Vial of 500 ml containing 1000 doses
Box of 1 vial of 500 ml containing 1000 doses
Box of 5 vial of 500 ml containing 1000 doses

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/11/2016

10 DATE OF REVISION OF THE SUMMARY OF PRODUCT CHARACTERISTICS

November 2016